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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., **Plaintiff,** **v.** **SUN PHARMA GLOBAL FZE, SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES LIMITED,** **Defendants.**	**Civil Action No. 19-15678 (SDW)(CLW)** **DEFENDANTS' ANSWER TO FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

ANSWER OF DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMA GLOBAL FZE., AND SUN PHARMA GLOBAL INC. TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Sun Pharmaceutical Industries Limited ("SPIL"), Sun Pharmaceuticals Industries, Inc. ("SPII"), Sun Pharma FZE ("Sun FZE") and Sun Pharma Global Inc. ("SPGI") (collectively, "Defendants" or "Sun"), by their undersigned attorneys, answer the First Amended Complaint of Corcept Therapeutics, Inc. ("Corcept") as follows:

Response to "Nature of the Action"

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Sun's filing of an Abbreviated New Drug Application ("ANDA") No. 213387 ("Sun's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Corcept's 300 mg mifepristone drug product ("Sun's Proposed Product") prior to the expiration of United States Patent Nos. 8,921,348 ("the '348 Patent"),10,195,214 ("the '214 Patent"), and 9,829,495 ("the '495 Patent") and 10,500,216 ("the '216 patent") (together, "the patents-in-suit"), owned by Corcept.

ANSWER: Defendants admit Corcept purports to bring its claims under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* Defendants further admit this action purports to relate to ANDA No. 213387, in which SPIL, with SPII as its U.S. Agent, seeks approval to market a generic version of a mifepristone drug product prior to the expiration of the '348 Patent, the '214 Patent, the '495 Patent and the '216 Patent. Defendants deny any remaining allegations in Paragraph 1.

Response to "The Parties"

2. Plaintiff Corcept is a biopharmaceutical company committed to improving the lives of patients worldwide. Corcept focuses on, and heavily invests in, the discovery and development of drugs that regulate the effects of cortisol for the treatment of severe and life-threatening conditions, including Cushing's syndrome. Corcept is an industry leader for the development of orphan-status rare disease drugs, including KORLYM®. Corcept is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 149 Commonwealth Dr., Menlo Park, CA 94025.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 2 and therefore deny the same.

3. On information and belief, defendant Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone, P.O. Box #122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly-owned subsidiary of Sun Ltd.

ANSWER: Defendants admit Sun FZE is a corporation organized and existing under the laws of the Sharjah, United Arab Emirates, has its principal place of business in United Arab Emirates, and is wholly-owned by SPIL.

4. On information and belief, defendant Sun Pharma is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Pharma is a wholly-owned subsidiary of Sun Ltd.

ANSWER: Defendants admit SPGI is a corporation organized and existing under the laws of the British Virgin Islands, maintains an address in the British Virgin Islands, and is wholly-owned by SPIL.

5. On information and belief, defendant Sun Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

ANSWER: Defendants admit SPII is a corporation organized under the laws of the State of Michigan, has a principal place of business in New Jersey and is wholly-owned by SPIL.

6. On information and belief, defendant Sun Ltd. is a corporation organized and existing under the laws of existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India.

ANSWER: Defendants admit SPIL is a corporation organized and existing under the laws of India and has its principal place of business in Mumbai, Maharashtra, India.

Response to "The Patents-in-Suit"

7. On December 30, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '348 Patent, entitled "Optimizing Mifepristone Levels

in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '348 Patent is attached hereto as Exhibit A.

ANSWER: Defendants admit the '348 patent on its face indicates an issue date of December 30, 2014 and is entitled "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists." Defendants further admit the '348 patent on its face lists Corcept as an assignee and lists the inventor as Joseph K. Belanoff. Defendants further admit what appears to be a copy of the '348 patent is attached to Plaintiffs' Complaint as Exhibit A. Defendants deny "the USPTO duly and lawfully issued the '348 patent" and deny any remaining allegations in Paragraph 7.

8. On February 5, 2019, the USPTO duly and lawfully issued the '214 Patent, entitled, "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '214 Patent is attached hereto as Exhibit B.

ANSWER: Defendants admit the '214 patent on its face indicates an issue date of February 5, 2019 and is entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors." Defendants further admit the '214 patent on its face lists Corcept as an assignee and lists the inventor as Joseph K. Belanoff. Defendants further what appears to be a copy of the '214 patent is attached to Plaintiffs' Complaint as Exhibit B. Defendants deny "the USPTO duly and lawfully issued the '214 patent" and deny any remaining allegations in Paragraph 8.

9. On November 28, 2017, the USPTO duly and lawfully issued the '495 Patent, entitled, "Method for Differentially Diagnosing ACTH-Dependent Cushing's Syndrome" to Corcept as assignee of the inventor Andreas G. Moraitis. A copy of the '495 Patent is attached hereto as Exhibit C.

ANSWER: Defendants admit the '495 patent on its face indicates an issue date of November 28, 2017, and is entitled "Method for Differentially Diagnosing ACTH-Dependent

Cushing's Syndrome." Defendants further admit the '495 patent on its face lists Corcept as an assignee and lists the inventor as Andreas G. Moraitis. Defendants further admit what appears to be a copy of the '495 patent is attached to Plaintiffs' Complaint as Exhibit C. Defendants deny "the USPTO duly and lawfully issued the '495 patent" and deny any remaining allegations in Paragraph 9.

10. On December 10, 2019 the USPTO duly and lawfully issued the '216 Patent, entitled, "Optimizing Mifepristone Absorption" to Corcept as assignee of the inventors Joe Belanoff, Robert Roe, and Caroline Loewy. A copy of the '216 Patent is attached hereto as Exhibit D.

ANSWER: Defendants admit the '216 patent on its face indicates an issue date of December 10, 2019, and is entitled "Optimizing Mifepristone Absorption." Defendants further admit the '216 patent on its face lists Corcept as an assignee and lists the inventors as Joe Belanoff, Robert Roe, and Caroline Loewy. Defendants further admit what appears to be a copy of the '216 patent is attached to Plaintiffs' First Amended Complaint as Exhibit D. Defendants deny "the USPTO duly and lawfully issued the '216 patent" and deny any remaining allegations in Paragraph 10.

Response to "The KORLYM® Drug Product"

11. Corcept holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for mifepristone tablets (NDA No. 202107), which it sells under the trade name KORLYM. KORLYM® is an FDA-approved medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. The claims of the patents-in-suit cover, inter alia, methods of use and administration of mifepristone.

ANSWER: Defendants admit the Orange Book lists Corcept as the NDA holder for NDA No. 202107 for mifepristone tablets sold under the trade name Korlym. Defendants further admit the prescribing information for Korlym, on its face, specifies Korlym to be a medication

approved by the FDA for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Defendants deny any remaining allegations in Paragraph 11.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Product with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to KORLYM®.

ANSWER: Defendants admit the patents-in-suit are listed in the Orange Book with respect to Korlym, and that this listing is made pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Defendants deny any remaining allegations in Paragraph 12.

Response to "Jurisdiction and Venue"

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in Paragraph 13 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 13.

14. The Court has personal jurisdiction over Sun by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

ANSWER: The allegations in Paragraph 14 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 14. Defendants Sun FZE and SPGI deny any allegations that the Court has jurisdiction in this case. For the purposes of this action only, SPIL and SPII do not contest personal jurisdiction.

15. On information and belief, Sun FZE, Sun Pharma, Sun Inc., and Sun Ltd. develop, manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including within this Judicial District.

ANSWER: Defendants deny the allegations in Paragraph 15.

16. On information and belief, Sun FZE, Sun Pharma, Sun Inc., and Sun Ltd. prepare and/or aid in the submission of ANDAs to the FDA.

ANSWER: Defendants admit they have previously prepared and/or aided in the submission of ANDAs to the FDA. Defendants deny Sun FZE or SPGI have any interest in or connection with ANDA No. 213387. Defendants deny any remaining allegations in Paragraph 16.

17. On information and belief, Sun FZE, Sun Pharma, Sun Inc., and Sun Ltd. derive substantial revenue from selling generic products throughout the United States, including in this Judicial District.

ANSWER: Defendants deny the allegations in Paragraph 17.

18. This Court has personal jurisdiction over Sun because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Sun intends a future course of conduct that includes acts of patent infringement in New Jersey.

ANSWER: Defendants deny they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and deny they intend a future course of conduct that includes acts of patent infringement in New Jersey. Defendants Sun FZE and SPGI deny any allegations that the Court has jurisdiction in this case. For the purposes of this action only, SPIL and SPII do not contest personal jurisdiction.

19. On information and belief, Sun FZE, Sun Pharma, Sun Inc., and Sun Ltd. actively participated in the submission of Sun's ANDA. On information and belief, Sun Ltd. will work in concert with Sun FZE, Sun Pharma, Sun Inc., and/or other subsidiaries towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Sun's Proposed Product, throughout

the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

ANSWER: Defendants deny the allegations in Paragraph 19.

20. On information and belief, Sun seeks approval from the FDA to sell Sun's Proposed Product throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Sun's ANDA.

ANSWER: Defendants admit SPIL is the applicant for ANDA No. 213387 seeking approval from the FDA to sell its proposed ANDA product throughout the United States. Defendants admit SPII serves as the United States agent for SPIL's ANDA submission. Sun FZE and SPGI have no interest in or connection to Sun's ANDA and deny the allegations in Paragraph 20. Defendants deny any remaining allegations in Paragraph 20.

21. This Court has personal jurisdiction over Sun because Sun has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun regularly and continuously transacts business within New Jersey, directly or indirectly, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. For example, Sun's website states its "US headquarters are in Cranbury, New Jersey," it has "distribution and customer service teams at multiple locations across the country," and "Sun Pharma's latest acquisition of a majority interest in Ranbaxy Laboratories Limited (Ranbaxy) and its Ohm Laboratories facilities in . . . New Jersey makes it the largest Indian pharma company in the US market." Sun Pharma USA, http://www.sunpharma.com/usa (last visited June 28, 2019).

ANSWER: Paragraph 21 contains conclusions of law to which no answer is required. To the extent an answer is required, Defendants admit they have transacted business within New Jersey. Defendants further admit that the website referenced in Paragraph 21 contained the language quoted therein as of June 28, 2019. Defendants Sun FZE and SPGI deny any allegations that the Court has jurisdiction over them in this case. For the purposes of this action only, SPIL and SPII do not contest personal jurisdiction. Defendants deny any remaining allegations in Paragraph 21.

22. This Court has personal jurisdiction over Sun FZE by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun FZE purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: The allegations in Paragraph 22 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the Court has jurisdiction over Sun FZE in this case and Defendants further deny any remaining allegations in Paragraph 22.

23. On information and belief, Sun FZE is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Defendants deny the allegations in paragraph 23.

24. On information and belief, Sun FZE, alone or through Sun Pharma, Sun Inc., and/or Sun Ltd., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

ANSWER: Defendants deny the allegations in Paragraph 24.

25. On information and belief, Sun FZE has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Novartis Pharmaceuticals Corp., et al. v. Sun Pharma Global FZE, et al.*, Civil Action No. 12-4393 (SDW)(MCA); *The Medicines Co. v. Sun Pharma Global FZE, et al.*, Civil Action No. 11-6819 (PGS)(DEA).

ANSWER: Defendants admit Sun FZE has previously not contested jurisdiction and has filed counterclaims in the District of New Jersey. Defendants deny any allegations that the Court has jurisdiction over Sun FZE in this case. Defendants deny any remaining allegations in Paragraph 25.

26. In the alternative, this Court has personal jurisdiction over Sun FZE because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Corcept's claims arise under federal law; (b) Sun FZE is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun FZE has sufficient contacts with the United

States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun FZE satisfies due process.

ANSWER: The allegations in Paragraph 26 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants state Sun FZE has no interest in or connection with ANDA No. 213387 and deny any allegations that the Court has jurisdiction over Sun FZE in this case. Defendants deny any remaining allegations in Paragraph 26.

27. This Court has personal jurisdiction over Sun Pharma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Pharma purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: The allegations in Paragraph 27 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants any allegations that the Court has jurisdiction over SPGI in this case and Defendants further deny any remaining allegations in Paragraph 27.

28. On information and belief, Sun Pharma is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Defendants deny the allegations in Paragraph 28.

29. On information and belief, Sun Pharma, alone or through Sun FZE, Sun Inc., and/or Sun Ltd., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

ANSWER: Defendants deny the allegations in Paragraph 29.

30. On information and belief, Sun Pharma has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g., Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 14-4307 (JBS)(KMW); *Otsuka Pharm. Co. v. Sun*

Pharm. Indus. Ltd., et al., Civil Action No. 14-6397 (JBS) (KMW); *Aventis Pharms. Inc., et al. v. Sun Pharma Global Inc., et al.*, Civil Action No. 09-325 (GEB)(MCA).

ANSWER: Defendants admit SPGI has previously not contested jurisdiction and has filed counterclaims in the District of New Jersey. Defendants deny any allegations that the Court has jurisdiction over SPGI in this case. Defendants deny any remaining allegations in Paragraph 30.

31. In the alternative, this Court has personal jurisdiction over Sun Pharma because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Corcept's claims arise under federal law; (b) Sun Pharma is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Pharma has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Pharma satisfies due process.

ANSWER: The allegations in Paragraph 31 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants note SPGI has no interest in or connection with ANDA No. 213387 and denies any allegations that the Court has jurisdiction over SPGI in this case. Defendants deny any remaining allegations in Paragraph 31.

32. This Court has personal jurisdiction over Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Inc. purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: The allegations in Paragraph 32 comprise conclusions of law to which no answer is required. To the extent an answer is required, SPII denies the allegations in Paragraph 32, but does not contest personal jurisdiction for the purposes of this action only.

33. On information and belief, Sun Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Defendants admit SPII is in the business of, among other things, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district. Defendants deny any remaining allegations in Paragraph 33.

34. On information and belief, Sun Inc., alone or through Sun FZE, Sun Pharma, and/or Sun Ltd., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

ANSWER: Defendants admit SPII acts as the U.S. agent for SPIL and in that role, alone or through others, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Defendants deny the remaining allegations in Paragraph 34.

35. On information and belief, Sun, through at least Sun Inc., maintains physical places of business in at least Princeton, New Jersey and Cranbury, New Jersey.

ANSWER: Defendants admit SPII maintains a physical place of business in New Jersey. Defendants deny any remaining allegations in Paragraph 35.

36. On information and belief, Sun Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132 and is registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437.

ANSWER: Defendants SPII admit the allegations in Paragraph 36.

37. On information and belief, Sun Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Janssen Pharms. Inc. v Sun Pharma Global FZE, et al.*, Civil Action No. 11-6089 (SRC)(CLW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 14-4307 (JBS)(KMW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, Civil Action No. 14-6397 (JBS)(KMW).

ANSWER: Defendants admit SPII has previously not contested personal jurisdiction and asserted counterclaims in this judicial district. For the purposes of this action only, SPII does not contest personal jurisdiction. Defendants deny any remaining allegations in Paragraph 37.

38. On information and belief, Sun FZE, Sun Global, and Sun Inc. act for the benefit of and at the direction of Sun Ltd., and are agents and/or alter egos of Sun Ltd.

ANSWER: Defendants deny the allegations in Paragraph 38.

39. This Court has personal jurisdiction over Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Ltd. purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: The allegations in Paragraph 39 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 39. For the purposes of this action only, SPIL does not contest personal jurisdiction.

40. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Defendants admit SPIL is in the business of, among other things, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, in the United States, including within this judicial district. Defendants deny any remaining allegations in Paragraph 40.

41. On information and belief, Sun Ltd., alone or through Sun FZE, Sun Pharma, and/or Sun Inc., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

ANSWER: Defendants admit SPIL, alone or through others, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Defendants deny any remaining allegations in Paragraph 41.

42. This Court also has personal jurisdiction over Sun Ltd. because Sun Ltd. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Ltd. regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey.

ANSWER: The allegations in Paragraph 42 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 42. For the purposes of this action only, SPIL does not contest personal jurisdiction.

43. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Sun Inc., a company registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, Sun Inc. On information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd., and is controlled and/or dominated by Sun Ltd.

ANSWER: The allegations in Paragraph 43 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 43. For the purposes of this action only, SPIL does not contest personal jurisdiction.

44. On information and belief, Sun Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

ANSWER: Defendants admit SPIL has previously not contested personal jurisdiction in this judicial district. Defendants deny any remaining allegations in Paragraph 44.

45. Sun Ltd. has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and has not challenged personal jurisdiction. *See, e.g.*, *Jazz Pharmaceuticals, Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-8229 (ES)(JAD); *Boehringer Ingelheim Pharmaceuticals Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-5982 (PGS)(TJB); *Jazz Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-3217 (ES)(JAD); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 14-6397 (JBS)(KMW); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 14-4307 (JBS)(KMW); *Cephalon, Inc. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 11-5474 (FLW)(DEA); *Depomed, Inc., et al. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 11-3553 (JAP)(TJB).

ANSWER: Defendants admit SPIL has been sued and has filed counterclaims in this judicial district in one or more prior cases and, in certain of those cases, has not challenged personal jurisdiction. Defendants deny any remaining allegations in Paragraph 45.

46. Sun Ltd. has further availed itself of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g.*, *Sun Pharmaceutical Industries Ltd., et al. v. Altana Pharma AG, et al.*, Civil Action No. 05-2391.

ANSWER: Defendants admit SPIL filed suit in the above-mentioned case in this judicial district. Defendants deny any remaining allegations in Paragraph 46.

47. In the alternative, this Court has personal jurisdiction over Sun Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Corcept's claims arise under federal law; (b) Sun Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

ANSWER: The allegations in paragraph 47 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 47. For the purposes of this action only, SPIL does not contest personal jurisdiction.

48. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: The allegations in paragraph 48 comprise conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations in Paragraph 48. For the purposes of this action only, SPIL and SPII do not contest venue.

Response to "Acts Giving Rise To This Suit"

49. Pursuant to Section 505 of the FFDCA, Sun filed ANDA No. 213387 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sun's Proposed Product, before the patents-in-suit expire.

ANSWER: Defendants admit SPIL, through its U.S. Agent SPII, filed ANDA No. 213387 pursuant to the patent laws and seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the product proposed in the ANDA prior to the expiration of the patents-in-suit. Defendants deny Sun FZE and SPGI filed ANDA No. 213387. Neither Sun FZE or SPGI have any interest in or connection with ANDA No. 213387 and deny the allegations in Paragraph 49. Defendants deny any remaining allegations in Paragraph 49.

50. No earlier than June 07, 2019, Sun sent written notice of a Paragraph IV Certification ("Sun's Notice Letter") to Corcept. According to Sun's Notice Letter, Sun filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product before expiration of the patents listed in the Orange Book with respect to KORLYM®.

ANSWER: Defendants admit, on June 7, 2019, SPIL sent its Notice Letter to Corcept. Defendants further admit, according to the notice letter, SPIL seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of SPIL's proposed product before expiration of the patents listed in the Orange Book with respect to KORLYM® pursuant to the patent laws. Defendants Sun FZE and SPGI did not send the Notice Letter to Corcept and do not have any interest in or connection with ANDA No. 213387 and therefore deny the allegations in Paragraph 50. Defendants deny any remaining allegations in Paragraph 50.

51. Sun's Notice Letter alleges that the claims of the patents-in-suit patent are invalid and/or will not be infringed by the activities described in Sun's ANDA.

ANSWER: Defendants admit in the Notice Letter SPIL alleges the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in SPIL's ANDA. Sun FZE and SPGI do not have any interest in or connection with ANDA No. 213387 and do not have knowledge concerning the Notice Letter and therefore deny the allegations in Paragraph 51. Defendants deny any remaining allegations in Paragraph 51.

52. On information and belief, in connection with the filing of its ANDA as described above, Sun provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's ANDA.

ANSWER: SPIL admits that, in connection with the filing of its ANDA, it provided a written certification to the FDA pursuant to the patent laws alleging that the claims of the '348, the '214 and the '495 patents are invalid, unenforceable, and/or will not be infringed by the activities described in SPIL's ANDA. Sun's Notice Letter and the original complaint were sent and filed prior to the issuance of the '216 patent. To date, Sun has not yet certified to the '216 patent. SPII admits it serves as the United States agent of SPIL with respect to ANDA No. 213387. Sun FZE and SPGI do not have any interest in or connection with ANDA No. 213387 and were not involved in the filing of ANDA No. 213387 and deny the allegations in Paragraph 52. Defendants deny any remaining allegations in Paragraph 52.

53. On information and belief, following FDA approval of Sun's ANDA, Sun FZE, Sun Pharma, Sun Inc., and Sun Ltd. will work in concert with one another to make, use, offer to sell, or sell Sun's Proposed Product throughout the United States, or import such generic products into the United States.

ANSWER: Defendants deny the allegations in paragraph 53.

Response to "Count I: Infringement of the '348 Patent"

54. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and reallege their answers to the allegations of the preceding paragraphs as if fully set forth herein.

55. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '348 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 55 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 55.

56. A justiciable controversy exists between the parties hereto as to the infringement of the '348 Patent.

ANSWER: Paragraph 56 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 56.

57. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

ANSWER: Paragraph 57 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 57.

58. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '348 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '348 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 58 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 58.

59. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '348 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 59 contains conclusions of law to which no response is required. To the extent a further response is required, Defendants deny the allegations in Paragraph 59.

60. Failure to enjoin Sun's infringement of the '348 Patent will substantially and irreparably damage Corcept.

ANSWER: Paragraph 60 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 60.

61. Corcept does not have an adequate remedy at law.

ANSWER: Paragraph 61 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 61.

Response to "Count II: Infringement of the '214 Patent"

62. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and reallege their answers to the allegations of the preceding paragraphs as if fully set forth herein.

63. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '214 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 63 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 63.

64. A justiciable controversy exists between the parties hereto as to the infringement of the '214 Patent.

ANSWER: Paragraph 64 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 64.

65. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

ANSWER: Paragraph 65 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 65.

66. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '214 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '214 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 66 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 66.

67. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '214 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 67 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 67.

68. Failure to enjoin Sun's infringement of the '214 Patent will substantially and irreparably damage Corcept.

ANSWER: Paragraph 68 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 68.

69. Corcept does not have an adequate remedy at law.

ANSWER: Paragraph 69 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 69.

Response to "Count III: Infringement of the '495 Patent"

70. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and reallege their answers to the allegations of the preceding paragraphs as if fully set forth herein.

71. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '495 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 71 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 71.

72. A justiciable controversy exists between the parties hereto as to the infringement of the '495 Patent.

ANSWER: Paragraph 72 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 72.

73. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '495 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

ANSWER: Paragraph 73 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 73.

74. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '495 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally

encourage acts of direct infringement with knowledge of the '495 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 74 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 74.

75. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '495 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '495 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 75 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 75.

76. Failure to enjoin Sun's infringement of the '495 Patent will substantially and irreparably damage Corcept.

ANSWER: Paragraph 76 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 76.

77. Corcept does not have an adequate remedy at law.

ANSWER: Paragraph 77 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 77.

Response to "Count IV: Infringement of the '216 Patent"

78. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants repeat and reallege their answers to the allegations of the preceding paragraphs as if fully set forth herein.

79. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the

expiration of the '216 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 79 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 79.

80. A justiciable controversy exists between the parties hereto as to the infringement of the '216 Patent.

ANSWER: Paragraph 80 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 80.

81. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '216 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

ANSWER: Paragraph 81 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 81.

82. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '216 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '216 Patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 82 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 82.

83. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '216 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '216 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 83 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 83.

84. Failure to enjoin Sun's infringement of the '216 Patent will substantially and irreparably damage Corcept.

ANSWER: Paragraph 84 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 84.

85. Corcept does not have an adequate remedy at law.

ANSWER: Paragraph 85 contains conclusions of law to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 85.

Response to "PRAYER FOR RELIEF"

Defendants deny Corcept is entitled to judgment or any of the relief prayed for in paragraphs (A) through (K) under the heading "PRAYER FOR RELIEF" in the complaint. Defendants demand judgment in their favor.

AFFIRMATIVE DEFENSES OF DEFENDANTS

Without prejudice to the denials set forth in their Answer, Defendants plead the following affirmative defenses in response to Plaintiff's allegations. Defendants reserve the right to allege any and all defenses not presently known or revealed during discovery or other analysis.

First Affirmative Defense

This Court lacks personal jurisdiction over Defendants Sun FZE and SPGI.

Second Affirmative Defense

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

Third Affirmative Defense

The claims of the patents-in-suit are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

Fourth Affirmative Defense

Defendants have not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the patents-in-suit.

Fifth Affirmative Defense

Plaintiff may not seek injunctive relief against Defendants for at least the reason that Plaintiff's alleged damages are not immediate or irreparable and Plaintiff therefore has an adequate remedy at law.

Additional Defenses

Defendants reserve the right to allege additional affirmative defenses as they become known through the course of discovery.

WHEREFORE, Defendants pray this Court:

A. enter an order dismissing the First Amended Complaint, with prejudice, and denying Plaintiffs the relief requested in the First Amended Complaint and any relief whatsoever;

B. deny Plaintiff any award of damages, costs, or fees;

C. declare this case exceptional under 35 U.S.C. § 285 and award Defendants reasonable attorneys' fees;

D. award Defendants their costs; and

E. grant such other and further relief as this Court may deem just.

COUNTERCLAIMS OF DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD

Without admitting any of the allegations of Corcept Therapeutics, Inc. ("Counterclaim Defendant") other than those expressly admitted herein, and without prejudice to Defendant-Counterclaimant Sun Pharmaceutical Industries Ltd. ("SPIL") to plead additional counterclaims as the facts of the matter warrant, Sun asserts the following counterclaims against Counterclaim Defendant.

Nature Of The Action

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that SPIL's proposed products in Abbreviated New Drug Application ("ANDA") No. 213387 do not and will not infringe any valid and enforceable claim of U.S. Patent Nos. 8,921,348 ("the '348 Patent") and 9,829,495 ("the '495 Patent"), and that each and every claim of the '348, '495, 10,195,214 ("the '214 Patent") and 10,500,216 ("the '216 Patent") patents (together, "the patents-in-suit") are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

The Parties

2. Defendant-Counterclaimant SPIL is a corporation organized and existing under the law of India, having a principal place of business in Mumbai, Maharashtra, India.

3. On information and belief, and based on Counterclaim Defendants' allegations, counterclaim defendant Corcept is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 149 Commonwealth Dr., Menlo Park, CA 94025.

4. On information and belief, and based on Counterclaim Defendants' allegations, Corcept, by themselves and/or through their affiliates and agents, are in the business of, *inter alia*, developing, manufacturing and obtaining regulatory approval of branded pharmaceutical products for distribution and sale through the United States, including within this judicial district.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This Court has personal jurisdiction over Counterclaim Defendants based on, *inter alia,* their filing of this lawsuit in this jurisdiction.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

Background

8. According to the United States Food & Drug Administration ("FDA") publication titled *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book"), Corcept holds an approved New Drug Application ("NDA"), No. 202107, for mifepristone tablets marketed under the trade name KORLYM®.

9. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to the FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug." The FDA ministerially publishes these patents in the Orange Book.

10. Upon information and belief, and as stated in the Complaint in this matter, Corcept is the owner and assignee of the '348, '495, '214 and '216 patents.

11. Upon information and belief, Corcept, itself or through its agents, caused the '348, '495, '214 and '216 patents to be listed in the Orange Book as patents that claim KORLYM ® or methods of using KORLYM®.

The '348, '495, '214 and '216 Patents Listed in the Orange Book for KORLYM®

12. The '348 patent, on its face, is titled "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists" and has an issue date of December 30, 2014.

13. On the face of the '348 patent, the assignee is Corcept Therapeutics, Inc. Upon information and belief, including Corcept's allegations, Corcept is the owner and/or licensee of the '348 patent.

14. The '495 patent, on its face, is titled "Method for Differentially Diagnosing ACTH-Dependent Cushing's Syndrome" and has an issue date of November 28, 2017.

15. On the face of the '495 patent, the assignee is Corcept Therapeutics, Inc. Upon information and belief, including Corcept's allegations, Corcept is the owner and/or licensee of the '348 patent.

16. The '214 patent, on its face, is titled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors" and has an issue date of February 5, 2019.

17. On the face of the '214 patent, the assignee is Corcept Therapeutics, Inc. Upon information and belief, including Corcept's allegations, Corcept is the owner and/or licensee of the '214 patent.

18. The ’216 patent, on its face, is titled “Optimizing mifepristone absorption” and has an issue date of December 10, 2019.

19. On the face of the ’216 patent, the assignee is Corcept Therapeutics, Inc. Upon information and belief, including Corcept’s allegations, Corcept is the owner and/or licensee of the ’216 patent.

ANDA No. 213387 And The Notice Letter

20. SPIL submitted ANDA No. 213387 to the FDA, seeking approval to engage in commercial manufacture, or sale of mifepristone (“SPIL’s ANDA Product”) prior to the expiration of the ’348, ’495, ‘214 and the ’216 patents.

21. ANDA No. 213387 contained a Paragraph IV certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the ’348, ’495, and the 214 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale or importation into the United States of SPIL’s ANDA Product.

22. On or about June 7, 2019, SPIL sent a notice letter providing notice of its submission of ANDA No. 213387 to FDA (“the Notice Letter”) to Corcept. The Notice Letter contains notification of SPIL’s Paragraph IV Certification to FDA that ’348, ’495, and the ’214 patents are invalid and/or not infringed by the commercial manufacture, use or sale of SPIL’s ANDA Product.

23. On or around July 22, 2019, Counterclaim Defendants filed a lawsuit alleging infringement of the ’348, ’495, and the ’214 patents based on SPIL’s filing of ANDA No. 213387.

24. On January 23, 2020, Corcept filed its First Amended Complaint additionally alleging Sun infringes the ‘216 patent based on SPIL’s filing of ANDA No. 213387.

25. SPIL denies it infringes any valid claim of the ’348, ’495, ’214 and ’216 patents.

26. Unless enjoined, Corcept will continue to assert that SPIL infringes the ’348, ’495, ’214 and ’216 patents and will continue to impair SPIL’s ability to market its ANDA product, causing irreparable harm to SPIL’s business.

COUNT I
(Declaration of Invalidity of the ’348 Patent)

27. SPIL incorporates by reference Paragraphs 1 through 26 of its Counterclaims as if fully set forth herein.

28. There is an actual, substantial and continuing case or controversy between SPIL and Corcept regarding, *inter alia*, the invalidity of the ’348 patent.

29. For at least the reasons set forth in the Notice Letter of June 7, 2019, one or more of the claims of the ’348 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 et seq., including, e.g., §§ 102, 103, 112, and/or other judicially created bases for invalidation.

30. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq*., SPIL is entitled to declaratory judgment that one or more claims of the ’348 patent are invalid.

COUNT II
(Declaration of Invalidity of the ’495 Patent)

31. SPIL incorporates by reference Paragraphs 1 through 30 of its Counterclaims as if fully set forth herein.

32. There is an actual, substantial and continuing case or controversy between SPIL and Corcept regarding, *inter alia*, the invalidity of the ’495 patent.

33. For at least the reasons set forth in the Notice Letter of June 7, 2019, one or more of the claims of the ’495 patent are invalid for failure to comply with one or more of the

requirements set forth in 35 U.S.C. § 101 et seq., including, e.g., §§ 102, 103, 112, and/or other judicially created bases for invalidation.

34. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq*., SPIL is entitled to declaratory judgment that one or more claims of the '495 patent are invalid.

COUNT III
(Declaration of Invalidity of the '214 Patent)

35. SPIL incorporates by reference Paragraphs 1 through 34 of its Counterclaims as if fully set forth herein.

36. There is an actual, substantial and continuing case or controversy between SPIL and Corcept regarding, *inter alia*, the invalidity of the '214 patent.

37. For at least the reasons set forth in the Notice Letter of June 7, 2019, one or more of the claims of the '214 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 et seq., including, e.g., §§ 102, 103, 112, and/or other judicially created bases for invalidation.

38. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq*., SPIL is entitled to declaratory judgment that one or more claims of the '214 patent are invalid.

COUNT IV
(Declaration of Invalidity of the '216 Patent)

39. SPIL incorporates by reference Paragraphs 1 through 38 of its Counterclaims as if fully set forth herein.

40. There is an actual, substantial and continuing case or controversy between SPIL and Corcept regarding, *inter alia*, the invalidity of the '216 patent.

41. One or more of the claims of the '216 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 et seq., including, e.g., §§ 102, 103, 112, and/or other judicially created bases for invalidation.

42. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, SPIL is entitled to declaratory judgment that one or more claims of the '216 patent are invalid.

COUNT V
(Declaration of Noninfringement of the '348 Patent)

43. SPIL incorporates by reference Paragraphs 1 through 42 of its Counterclaims as if fully set forth herein.

44. There is an actual, substantial, and continuing case or controversy between SPIL and Counterclaim Defendants regarding, *inter alia*, SPIL's noninfringement of the '348 patent.

45. For at least the reasons set forth in the Notice Letter of June 7, 2019, the manufacture, use, sale, offer for sale, and/or important into the United States of the SPIL ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '348 patent either literally or under the doctrine of equivalents, at least because the SPIL ANDA Product is not covered by the claims of the '348 patent. Additionally, each of the claims of the '348 patent Counterclaim Defendant could assert against SPIL is invalid as set forth above in Count I of SPIL's Counterclaims. An invalid claim cannot be infringed.

46. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, SPIL is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '348 patent, either literally or under the doctrine of equivalents.

COUNT VI
(Declaration of Noninfringement of the '495 Patent)

47. SPIL incorporates by reference Paragraphs 1 through 46 of its Counterclaims as if fully set forth herein.

48. There is an actual, substantial, and continuing case or controversy between SPIL and Counterclaim Defendants regarding, *inter alia*, SPIL's noninfringement of the '495 patent.

49. For at least the reasons set forth in the Notice Letter of June 7, 2019, the manufacture, use, sale, offer for sale, and/or important into the United States of the SPIL ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '495 patent either literally or under the doctrine of equivalents, at least because the SPIL ANDA Product is not covered by the claims of the '495 patent. Additionally, each of the claims of the '495 patent Counterclaim Defendant could assert against SPIL is invalid as set forth above in Count II of SPIL's Counterclaims. An invalid claim cannot be infringed.

50. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, SPIL is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '495 patent, either literally or under the doctrine of equivalents.

COUNT VII
(Declaration of Noninfringement of the '214 Patent)

51. SPIL incorporates by reference Paragraphs 1 through 50 of its Counterclaims as if ully set forth herein.

52. There is an actual, substantial, and continuing case or controversy between SPIL and Counterclaim Defendants regarding, *inter alia*, SPIL's noninfringement of the '214 patent.

53. For at least the reasons set forth in the Notice Letter of June 7, 2019, the manufacture, use, sale, offer for sale, and/or important into the United States of the SPIL ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '214 patent either literally or under the

doctrine of equivalents, at least because the SPIL ANDA Product is not covered by the claims of the ’214 patent. Additionally, each of the claims of the ’214 patent Counterclaim Defendant could assert against SPIL is invalid as set forth above in Count III of SPIL’s Counterclaims. An invalid claim cannot be infringed.

54. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, SPIL is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the ’214 patent, either literally or under the doctrine of equivalents.

COUNT VIII
(Declaration of Noninfringement of the ’216 Patent)

55. SPIL incorporates by reference Paragraphs 1 through 54 of its Counterclaims as if fully set forth herein.

56. There is an actual, substantial, and continuing case or controversy between SPIL and Counterclaim Defendants regarding, *inter alia*, SPIL’s noninfringement of the ’216 patent.

57. The manufacture, use, sale, offer for sale, and/or important into the United States of the SPIL ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the ’216 patent either literally or under the doctrine of equivalents, at least because the SPIL ANDA Product is not covered by the claims of the ’216 patent. Additionally, each of the claims of the ’216 patent Counterclaim Defendant could assert against SPIL is invalid as set forth above in Count IV of SPIL’s Counterclaims. An invalid claim cannot be infringed.

58. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, SPIL is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the ’216 patent, either literally or under

the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, SPIL respectfully requests this Court enter judgment in its favor granting the following relief:

A. Declaration that all claims of the ’348 patent are invalid;

B. Declaration that all claims of the ’495 patent are invalid;

C. Declaration that all claims of the ’214 patent are invalid;

D. Declaration that all claims of the ’216 patent are invalid;

E. Declaration that all claims of the ’348 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the SPIL ANDA Product;

F. Declaration that all claims of the ’495 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the SPIL ANDA Product;

G. Declaration that all claims of the ’214 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the SPIL ANDA Product;

H. Declaration that all claims of the ’216 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the SPIL ANDA Product;

I. Declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding SPIL reasonable attorneys’ fees;

J. An award to SPIL of its costs and expenses in this action pursuant to 28 U.S.C. § 1920, or any other applicable statute; and

K. An award to SPIL of such other and further relief as the Court deems just and proper.

Dated: January 31, 2020

Respectfully submitted:

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CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that a true and correct copy of the foregoing **Answer of Defendants to Plaintiff's First Amended Complaint for Patent Infringement**, **Affirmative Defenses of Defendants and Counterclaims of Defendant Sun Pharmaceutical Industries Ltd.** was delivered to the following counsel by electronic mail through the U.S. District Court's efile notification system.

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